Subject: Update to the Important Device Field Information Letter Issued on March 7 2013 for LifeCare PCA™ infusers

Undetected Distal Occlusions Caused by a Worn Half Nut

August 29th, 2014

Dear Healthcare Professional,

Hospira Healthcare Corporation (Hospira) issued the attached Important Device Information on March 7 2013 due to reports of PCA pumps not detecting distal occlusions. This issue is caused by normal wear and tear on the half nut (the component/nut that travels up and down the lead screw) which prevents it from properly detecting the pressure build-up associated with a distal occlusion.

Notification	Impacted Product	Impacted product list number
Update to letter issued on March 7 2013	PCA™ Plus 2	List no. 01950-XX
	PCA™ Plus 3	List no. 12384-XX
	LifeCare PCA™ / LifeCare PCA™ with Hospira MedNet™	List no. 20709-XX

In the March 7, 2013 letter, Hospira recommended that facilities immediately inspect their PCA devices to determine if the half nut was worn and unable to effectively detect a distal occlusion by performing the following steps:

- Perform the Performance Verification Test (PVT) Occlusion Test as defined in the PCA Technical Service Manual (TSM);
- If your device does not pass the PVT Occlusion Test, remove it from clinical service and contact the Hospira Canadian Service Center to report the issue at 1-866-488-6088 Option 5 / 2 or by email at CanadaPumpSupport@hospira.com.

If your facility has not yet taken the above steps, Hospira recommends taking them immediately.

Additionally, Hospira committed to:

- Establish a useful life for the half nut;
- Add a requirement for an annual PVT Occlusion Test to the Technical Service Manual (TSM);
- Update the System Operating Manual (SOM) regarding proper vial resetting technique.

As such, Hospira is now informing you that:

- Hospira determined that the useful life of the half nut is sixty (60) months;
- the updated TSM, incorporating the annual PVT Occlusion Test requirement, is now available;
- the updated SOM, incorporating the proper vial resetting technique into section *Loading a Vial* (4-4 and 4-5), is now available.

Hospira recommends the following.

Instructions and recommended action List no. 20709 *LifeCare PCA*	1. Some LifeCare PCA / LifeCare PCA with Hospira MedNet devices may be older than or approaching the useful life of the half nut (60 months). As a result, Hospira will provide customers with replacement mechanisms containing a new half nut. Customers will have the option to replace the mechanisms themselves or ask Hospira for technical assistance. For customers electing to perform the replacement, Hospira will provide instructions for how to document and return the replaced mechanisms. Customers will be required to provide Hospira with the serial numbers of the devices, serial numbers of the mechanisms removed, serial numbers of the mechanisms installed and confirmation that the devices passed the PVT. Customers will also be required to return this information and the removed mechanisms. Hospira anticipates beginning this activity in Q4 2014. 2. Hospira has added a requirement to Section 5.2 of the TSM to replace the mechanism assembly at least once every sixty (60) months. Hospira has also incorporated into Section 5.2 of the TSM a requirement to perform a performance verification test (PVT) at least once every 12 months. The specific PVT Occlusion Test can be found in section 5.3.6 of the TSM. 3. Customers can download the updated TSM and SOM from the Hospira website at www.hospira.ca/english/newsandmedia.aspx. Hospira recommends that you provide the updated TSM and SOM to users in your facility as soon as possible. 4. Once you have downloaded both the updated TSM and SOM, please complete the attached reply form and return it to the fax number or e-mail address indicated on the form, even if you do not have the affected product. If you have further distributed these devices to the retail level, notify your accounts who may have received the product and ask them to complete and return the attached Reply Form to Hospira.

Instructions and recommended action List no. 01950 *PCA Plus 2* List no. 12384 *PCA Plus 3*	As a result of the May 2013, Hospira global device strategy press release, announcing the retirement of the legacy PCA (List Numbers 1950 and 12384), the above actions will only apply to the LifeCare PCA (List Number 20709). Users of legacy PCA should ensure to perform the PVT Occlusion Test as per the TSM instructions at least every 12 months and continue to follow the proper vial resetting technique outlined below: a. Grasp the cradle release mechanism and squeeze completely; b. Continue to squeeze the release mechanism during movement of the cradle; c. A grinding sound should not be audible and the release mechanism should slide freely to prevent damage. The instructions included in this letter contain all of the information that would have been added to the TSM and SOM for the legacy PCA.

Health Canada has been notified of this action.

For further inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Canadian Service Center	1-866-488-6088 Option 5 / 2 CanadaPumpSupport@hospira.com	To report adverse events or product complaints on the pump.
Hospira Clinical Support	1-866-488-6088 Option 4 mail-ClinSupport@hospira.com	For further clinical inquiries.

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Rania Al-Ammar
Regional Director, Commercial Quality

Reply Form – RESPONSE REQUIRED

LifeCare PCA™ Infusers
Update to Letter Important Device Field Information Issued on March 7 2013

Fax the completed form to 1-877-906-0208 or email to canadarecall@hospira.com

General Required Customer Information

Customer Number (ship to #)	Business Name
Address/City/ Province	Postal Code
Contact Name	Contact e-mail
Phone Number	Fax Number
Signature	Date

- I have received the letter and have notified users in my facility:
  - o ___YES
  - o ___NO; please state reason:_____
  - o ___Devices transferred/no longer owned; please indicate new owner contact information:
    - Business Name: _____
    - Address/City/State/ZIP:_____
    - Contact Name: _____
    - Contact Phone/E-mail Address: _____
  - o ___Other; please explain: _____

- Have you distributed the product further to the retail level?
  - o ___YES; if yes, have you notified your retail customers:
    - ___YES
    - ___NO; please explain:_____
  - o ___NO

- We intend to replace the mechanisms in our LifeCare PCA (ONLY List Number 20709) utilizing our own resources:
  - o ___YES
  - o ___NO; please explain: _____

- I have downloaded **BOTH** the updated LifeCare PCA Technical Service Manual (TSM) and the updated LifeCare PCA System Operating Manual (SOM) and provided/made available a copy to users in my facility.
  - o ___YES
  - o ___NO; please explain: _____

5.2
PREVENTIVE MAINTENANCE

Hospira requires that preventive maintenance be performed at least once every **12 months**. Replace components as required by visual inspection and test results.

Complete the ***Preventive Maintenance Checklist*** in ***Section 5.2.1***.

- The sealed, lead-acid battery must be replaced at least once every **24 months**.
- The mechanism assembly must be replaced at least once every **60 months** ***(see Figure 7-8)***.
- The coin cell battery must be replaced at least once every **120 months**.
- Perform the Performance Verification Test at least once every **12 months** along with the visual inspections.

Perform the preventive maintenance inspections and tests according to the following steps:

1. ***Section 5.2.1, Preventive Maintenance Checklist***
2. ***Section 5.2.2, AC Power Cord Inspection and Test***
3. ***Section 5.2.3, Front Enclosure, Rear Enclosure, Cradle Assembly, and Security Door Inspection and Test***
4. ***Section 5.2.4, Rubber Foot Pad Inspection***
5. ***Section 5.2.5, Pole Clamp Assembly Inspection and Test***
6. ***Section 5.2.6, Keypad, Displays (LED/LCD), and Indicators Inspection***
7. ***Section 5.2.7, Patient Pendant Inspection***
8. ***Section 5.2.8, Barcode Reader Window Inspection, Test, and Cleaning***

5.2.1
PREVENTIVE MAINTENANCE CHECKLIST

The **Preventive Maintenance** process must be performed at least once every 12 months to ensure proper performance of the PCA infuser. In addition, inspect the infusion system after repair or during cleaning. Replace any damaged or defective external parts as required.

Perform the **Performance Verification** tests as described in ***Section 5.3***, and replace components as described in ***Section 7***.

Hospira

LifeCare PCA with MedNet Infusion System

Preventive Maintenance Checklist

- Circle **PASS** or **FAIL** in the respective box after each inspection or test is performed.
- Enter the device model and serial number in the space provided.
- Sign and date this checklist in the space provided.

Item	Inspection	Test
AC Power Cord Inspection and Test	PASS / FAIL	PASS / FAIL
Front Enclosure, Rear Enclosure, Cradle Assembly, and Security Door Inspection and Test	PASS / FAIL	PASS / FAIL
Rubber Foot Pad Inspection	PASS / FAIL	
Pole Clamp Assembly Inspection and Test	PASS / FAIL	PASS / FAIL
Keypad, Displays (LED/LCD), and Indicators Inspection	PASS / FAIL	PASS / FAIL
Patient Pendant Inspection	PASS / FAIL	PASS / FAIL
Barcode Reader Window Inspection, Test, and Cleaning	PASS / FAIL	PASS / FAIL
Self Test		PASS / FAIL
Biomed Mode Tests		PASS / FAIL
Delivery Accuracy Test		PASS / FAIL
Occlusion Test		PASS / FAIL
Electrical Safety Test		PASS / FAIL
Connectivity Check		PASS / FAIL
	Battery Replaced?	YES / NO

TECHNICIAN	INFUSER
Signature: _____	Model: _____
Date: _____	Serial Number: _____

IMPORTANT DEVICE INFORMATION

LifeCare PCA™ Plus 2 – List Number 01950
LifeCare PCA™ 3 – List Number 12384
LifeCare PCA / LifeCare PCA with MedNet – List Number 20709

Undetected Distal Occlusions Caused by a Worn Half Nut

March 7, 2013

Dear Healthcare Professional:

Hospira, Inc. (Hospira) is issuing this letter because we have received reports of PCA pumps not detecting distal occlusions. This letter details the potential risk and recommended steps to take if you encounter this issue.

Affected Units: LifeCare PCA™ Plus 2 – List Number 01950
LifeCare PCA™ 3 – List Number 12384
LifeCare PCA / LifeCare PCA with MedNet – List Number 20709

Issue: This issue is caused by normal wear and tear on the Half Nut (the component/nut that travels up and down the lead screw) which prevents it from properly detecting the pressure build-up associated with a distal occlusion.

Risk to Health: Undetected distal occlusions could result in delay or interruption of therapy.

Required Action: Hospira recommends that facilities immediately inspect their PCA devices to determine if the half-nut is worn and unable to effectively detect a distal occlusion by performing the following steps:

- Perform the Performance Verification Test (PVT) Occlusion Test as defined in the PCA Technical Service Manual (TSM).
- If the device does not pass this test, remove it from clinical service and contact the Hospira Canadian Service Center at 1-866-488-6088 Option 5/2 to report the issue.
- Perform the appropriate troubleshooting and repair activities defined by your facility, which may include returning the device to Hospira for further diagnosis and servicing.

Hospira Actions: This issue is caused by normal wear and tear and is not the result of a defect, thus no corrective actions will be required to address this issue. Hospira is in the process of establishing a useful life for the half-nut, to determine when it will require replacement.

Additionally a requirement for an annual PVT Occlusion Test, to verify the proper operation of the half-nut is being developed. Both of these changes will be integrated into the Technical Service Manual in late 2013.

To reduce the excessive wear on the half nut resulting from incorrectly using the vial, information will be added to the System Operating Manual (SOM).

Health Canada has been notified of this action.

Please complete the attached reply form and return it to the fax number or e-mail address on the form, *even if you do not currently have the impacted devices.*

Hospira Healthcare Corporation
Corporation de soins de la santé Hospira
1111, boul. Dr.-Frederick-Philips Blvd., 6e étage / Suite 600
Saint-Laurent (Québec) Canada H4M 2X6

IMPORTANT DEVICE INFORMATION

LifeCare PCA™ Plus 2 – List Number 01950
LifeCare PCA™ 3 – List Number 12384
LifeCare PCA / LifeCare PCA with MedNet – List Number 20709

Undetected Distal Occlusions Caused by a Worn Half Nut

If you have further distributed these devices, please notify your accounts who may have received these devices from you and ask them to complete the attached reply form and to return it.

For further inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Canadian Service Center	1-866-488-6088 Option 5 / 2 CanadaPumpSupport@hospira.com	To report adverse events or product complaints
Hospira Clinical Support	1-866-488-6088 Option 4 mail-ClinSupport@hospira.com	For further clinical inquiries

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

Rania Al-Ammar
Regional Director, Commercial Quality